

REMARKS

Entry of the foregoing amendments, reconsideration and reexamination of the subject application, as amended, pursuant to and to and consistent with 37 C.F.R. §1.116, and in light of the remarks which follow are respectfully requested.

By the present amendment, claim 54 has been amended such that it is consistent with the elected subject matter, i.e., induction of T cell non-responsiveness to an autoantigen expressing cell. The cancelled subject matter (allergen expressing cell) will be submitted in a divisional application.

At the outset the Examiner is thanked for the courteous personal interview held on May 16, 2002. During the interview the Examiner indicated that he was to vacate the previous enablement rejection based on alleged insufficient demonstration that induction of T cell non-responsiveness to autoantigen expressing cells as he acknowledged that it is now accepted in the art that gp39 antagonists can be used to induce T cell non-responsiveness to antigen expressing cells.

Also, the written description aspect of the rejection was discussed. Examiner Gambel questioned whether isolated autoantigens were known at the time of the invention that are involved in specific autoimmune diseases. In response thereto, the undersigned advised the Examiner that evidence would be presented establishing that different autoantigens involved in autoimmune diseases had been characterized and were known at the time of the invention.

Turning now to the Office Action, claims 54-63 stand rejected under 35 U.S.C. §112 first paragraph based on enablement and written description grounds. The enablement aspect of the rejection is not specifically addressed as it is Applicant's understanding that he acknowledged at the recent interview this T cell non-responsiveness can be obtained to autoantigen expressing cells using gp39 antagonist as claimed herein.

The written description aspect of the rejection is based on the assertion that the specification does not identify precisely the specific autoantigens which may be used in the claimed methods. Absent such disclosure, it was suggested that claims 54-63 lack adequate written description from the as-filed disclosure.

However, as discussed at the interview, it was generally known at the time of the invention that various autoantigens were involved in specific autoimmune diseases and adverse immune responses associated therewith. Accordingly, while examples of such autoantigens are not expressly identified in the disclosure, this does not violate the written description requirement as suitable autoantigen would have been known at the time of the invention. To substantiate this fact, Applicants attach to this the one skilled in the art Reply a printout from a search conducted in the Medline database to identify articles that identify autoantigens involved in specific diseases known as of the filing date. Upon review of this printout it can be seen that numerous autoantigens involved in different autoimmune diseases including multiple sclerosis (myelin proteins), diabetes mellitus (islet antigens), arthritis (type II collagen), autoimmune encephalomyelitis, and autoimmune thyroid diseases had been known as of the date of the present invention. For the convenience of the Examiner, some of the more relevant citations are marked with an asterisk on the attached search printout.

Upon consideration thereof, it can be seen that the meaning of an autoantigen according to the invention would be readily appreciated by the skilled artisan.

Based on the foregoing, withdrawal of the §112 written description rejection of claims 54-63 is respectfully requested.

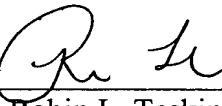
Claim 57 also stands rejected under 35 U.S.C. §112 second paragraph. This rejection is moot in view of the cancellation of this claim herein.

Based on the foregoing, it is anticipated that this application should be in condition for allowance. A Notice to that effect is respectfully solicited.

Respectfully submitted,

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Attachment:

Appendix

APPENDIX

54. (Twice Amended) A method for reducing T cell responses-responsiveness *in vivo* to an allergen or autoantigen expressing cell comprising administering to a subject in need of such treatment:

- (iii) an allergen or autoantigen expressing cell;
- (iv) a gp39 (CD40 ligand)-antagonist selected from the group consisting of an anti-gp39 antibody, an anti-gp39 antibody fragment that binds gp39, soluble CD40, and soluble CD40 fusion proteins;

wherein said gp39 antagonist is administered prior, concurrent and/or subsequent to administration of said allergen or autoantigen expressing cells, and said gp39 antagonist is administered in an amount effective to reduce T cell responses to said allergen or autoantigen expressing cells.